

## **REMARKS**

The Office Action dated August 11, 2003, has been received and reviewed. Claims 7-8 and 10-18 are pending in the present application. Claim 11 has been withdrawn from consideration and has been canceled without prejudice or disclaimer by the applicants. Claims 8, 10 and 12-17 are indicated to be allowable. Applicants thank the Examiner for indication of the allowable subject matter. Claims 7 and 18 stand rejected. Applicants respectfully request reconsideration of the rejections to Claims 7 and 18 in view of the arguments and remarks below.

### **I. Claim Amendments**

Claim 7 has been amended to recite the sequence identifier for the androgen receptor. Support for Claim 7 can be found throughout the specification and figures, particularly in figure 5.

### **II. Rejections Under 35 U.S.C. § 112, second paragraph**

Claims 7 and 18 stand rejected under 35 U.S.C. §112, second paragraph for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. § 112, second paragraph rejections in view of the claim amendments and the following remarks.

Specifically, Claims 7 and 18 stand rejected as allegedly the phrase "DNA sequence encoding human androgen receptor" does not have clear metes and bounds because no structure is provided in the claim limitation. Applicants respectfully disagree with this assessment. Applicants submit that the present application contains two examples of androgen receptor sequences (human and rat). Furthermore, this is the first instance where the androgen receptor sequence has been identified which would allow for characterization of its structure. Therefore, the present application does point out and distinctly claim the subject matter of the present invention as the present invention discloses a DNA sequence encoding human androgen receptor. However, in an effort to expedite the present application, Applicants have amended claim 7 to recite SEQ ID NO. 18. As Claim 18 depends from Claim 7, it is allowable for the same reasons. Accordingly, Applicants respectfully request

reconsideration and withdrawal of the 35 U.S.C. §112, second paragraph rejection to Claims 7 and 18.

### **III. Rejections under 35 U.S.C. § 112, first paragraph**

Claims 7 and 18 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention and as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse this rejection.

Applicants have amended Claim 7 to recite isolated and purified DNA sequence encoding human androgen receptor comprising SEQ ID NO: 18. As Claim 18 depends from Claim 7, it is allowable for the same reasons. In view of this claim amendment to Claim 7, withdrawal of the present rejection is respectfully requested.

### **IV. Rejections under 35 U.S.C. § 102(e)**

Claims 7 and 18 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Liao et al., US Patent No. 5,614,620. Applicants respectfully disagree with this rejection. Applicants respectfully traverse this rejection for the reasons set forth below.

Case law holds and the M.P.E.P. states that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Furthermore, the identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Additionally, anticipation under 35 U.S.C. § 102 requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention. *Apple Computer Inc. v. Articulate Systems Inc.* 57 USPQ2d 1057, 1061 (Fed. Cir. 2000). Liao et al. fails to disclose the subject matter contained in Claims 7 and 18.

As previously stated, the Liao patent does disclose and claim a full-length human androgen receptor protein, yet this full-length protein was not disclosed in the Liao et al. application filed on 30 March 1988. US Patent No. 5,614,620 to Liao et al. is based on

application SN 08/149,691, which is a continuation of 07/438,775, which is a continuation-in-part of SN 07/312,763; which is a continuation-in-part of 07/253,807 (filed 5 October 1988); which is a continuation-in-part of 07/176,107 (filed 30 March 1988).

**The present application was filed on 15 April 1988, two weeks after the initial Liao et al. application (SN 07/176,107) and almost six months before the second of the Liao et al. applications (SN 07/253,807).** The first Liao et al. application (the '107 application) provides an incomplete amino acid sequence for the human androgenic receptor. The '107 application was filed before sequence listings were required, and the sequences are provided only in the Figures. Only Figure 3 provides a DNA or amino acid sequence for the human androgen receptor.

The human androgen receptor sequences provided by Liao et al. in the '107 application (Figure 3) consist of approximately 2700 nucleotides encoding a protein of 733 amino acids. (A copy of the '107 file wrapper was provided in the parent application and will be resubmitted in the present application at the Examiner's request). The issued Liao et al. patent (US Patent No. 5,614,620) claims an isolated and purified DNA sequence of 3715 base pairs encoding a human androgen receptor of 909 amino acids. Applicants note that the first Liao et al. application (SN 07/176,107, filed March 30, 1988), to which the Examiner refers, describes an incomplete amino acid sequence for the human androgen receptor. The '107 application only discloses a truncated human androgen receptor protein of 733 amino acids encoded by a 2708 base pair DNA sequence (Figure 3; file history of '107 application provided with Amendment dated December 29, 1998). The '107 application does not disclose the full-length 909 amino acid sequence that is disclosed in the issued Liao et al. '620 patent (Figure 3). If the Examiner compares the sequences of Figure 3 of the '107 application and Figure 3C of the issued patent, it will be apparent that the final sequence includes an additional 188 amino acids at the amino terminal end of the protein. The androgen receptor amino acid sequence provided in the '107 application is thus only a portion of the final sequence provided in the issued patent.

In addition, the sequence of the human androgen receptor protein disclosed by Liao et al. in the '107 application is incorrect, *i.e.*, the first 27 amino acids shown in Figure 3 of the '107 application are erroneous. The correct sequence begins at amino acid residue 28 (*i.e.*, Thr Ser Ser), which is actually amino acid residue 217 in the correct, full-length human

androgen receptor sequence. Thus, the original application filed by Liao et al. discloses a sequence for the human androgen receptor protein that is both incomplete and incorrect.

Again, to reiterate this point, the '107 application describes the generation of an incomplete 2.6 kb cDNA encoding a 2.2 kb open reading frame by restriction digestion and ligation of over-lapping clones (Example 3, pages 11- 12 of the '107 application). In contrast, the issued '620 patent describes how a clone encoding the full-length human androgen receptor was generated by ligating the originally-described 2.6 kb sequence to an additional 1.6 kb sequence from a third overlapping clone to generate a 3715 base pair sequence encoding a full-length human androgen receptor ('620 patent, Example 3, Col. 9, lines 25-29). This additional work is not described in the '107 application and was added in a continuation-in-part application filed after the filing date of the present application.

For the reasons set forth above, Applicants submit that the sequence of the human androgen receptor protein disclosed by Liao et al., as of the filing date of the present application "has a materially different amino acid sequence" from the presently-claimed full-length human androgen receptor protein. Moreover, the disclosure of the full-length sequence in the '807 continuation-in-part-application (filed October 5, 1988) is not prior art against the present application. Accordingly, Applicants respectfully submit that the presently-claimed sequences are both novel and unobvious over Liao et al., and respectfully request that the rejection on this basis be withdrawn.

Thus, this matter was not disclosed by Liao et al. until continuation-in-part application serial no. 07/253,807 was filed on October 5, 1998. Therefore, the amino acid sequence of the full-length human androgen receptor of Liao et al. is only entitled to a priority date of October 5, 1998, *i.e.*, almost six months after the priority date of the present application. **Accordingly, this teaching in Liao et al. is not prior art against the present application.**

Furthermore, Applicants respectfully point out that even if Liao et al. taught such a material as claimed by the Examiner, neither Liao et al. nor one of ordinary skill in the art would have appreciated that the disclosed sequence was incorrect and, in fact, the correct sequence could be obtained from this putative material. Moreover, the structure of the claimed proteins and compositions would not have been obvious from any such uncharacterized material. Accordingly, Applicants respectfully submit that the claimed proteins and compositions are neither disclosed nor suggested by Liao et al.

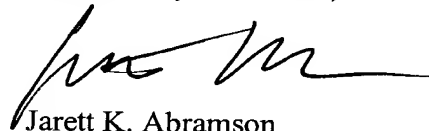
In view of the above, Applicants respectfully submit that the Liao et al. patent does not anticipate the present claims. Accordingly, withdrawal of the present rejection is respectfully requested.

### CONCLUSION

In view of the remarks presented herein, Applicants respectfully submit that the claims define patentable subject matter. If, in the opinion of the Examiner, a telephonic conference would expedite the examination of this matter, the Examiner is invited to call the undersigned attorney at (919) 854-1400.

It is not believed that an extension of time and/or additional fee(s)-including fees for net addition of claims-are required, beyond those that may otherwise be provided for in documents accompanying this paper. In the event, however, that an extension of time is necessary to allow consideration of this paper, such an extension is hereby petitioned under 37 C.F.R. §1.136(a). Any additional fees believed to be due in connection with this paper may be charged to our Deposit Account No. 50-0220.

Respectfully Submitted,



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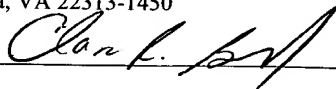
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